



California State Board of Pharmacy

1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

ORDER TO CEASE and DESIST

Date: 4/26/2013

Permit No. LSC-99606

Time of Day: 5:02 PM.

Name as shown on permit: Advance Outcome Management Inc.

Address: 12792 Valley View Street, Suite A

City: Garden Grove, CA 92845

Please be advised that it appears that there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the California State Board of Pharmacy:

California Code of Regulations section 1751.7 subdivision (a)(4) Written justification of the chosen expiration date for compounded sterile injectable products.

California Code of Regulations section 1751.7 subdivision (c) – Batch produced sterile injectable drugs products compounded from one or more non-sterile ingredient shall be subject to documented and product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

California Code of Regulations section 1751.4 subdivision (a)-no sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

California Code of Regulations section 1751.1 subdivision (b) – In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non sterile ingredients, the following records must be made and kept by the pharmacy:

- (3) Certification of the sterile compounding environment
- (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

California Code of Regulations section 1751.7 subdivision (a) (3) Actions to be taken in the event of a drug recall.


Pursuant to CA Business and Professions Code section 4127.3 Advance Outcome Management Inc. shall immediately cease and desist from furnishing sterile injectable compounded products.

Advance Outcome Management Inc. shall not furnish sterile injectable compounded products until such time as the board authorizes such furnishing.

California State Board of Pharmacy

Without admitting guilt, I hereby acknowledge that the law or regulation on which the above notice was issued has been explained to me and that I have received a copy of this notice.

By: 
Robert Kazebee & Valerie Sakamura Inspector

Signed: 
Title: President / PIC

Date: 4/26/2013

Any additional information (for example – corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent to my attention at the above address no later than 14 calendar days from date above. Please include a copy of this form with your information submitted.